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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/651,305

08/28/2003

Chia-Gee Wang

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EXAMINER

POLANSKY, GREGG

ART UNIT

PAPER NUMBER

1614

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/651,305	<b>Applicant(s)</b> WANG, CHIA-GEE	
	<b>Examiner</b> GREGG POLANSKY	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-24, 26-47, 49-59, 61-97 and 99 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 7, 12, 16-24, 26-36, 38, 40, 42, 47, 51-59, 61-65, 67, 69, 71, 76-88, 90, 92, 97 and 99 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4,6,8-11,14,15,37,39,41,43-46,49,50,66,68,70,72-75,89,91 and 93-96.

## **DETAILED ACTION**

### **Status of Claims**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/02/2009 has been entered.
2. Applicant's response, filed 6/02/2009, to the Office Action mailed 9/02/2008 is acknowledged.
3. The Declaration under 37 CFR 1.132 filed 6/02/2009 is sufficient, in combination with Applicant's arguments, to overcome the rejection of Claims 1, 3, 5, 7, 12, 16-24, 26-36, 38, 40, 42, 47, 51-59, 61-65, 67, 69, 71, 76-88, 90, 92, 97, and 99 under 35 U.S.C. 112 1<sup>st</sup> paragraph, lack of enablement. However, the Declaration is insufficient to overcome the rejection of Claims 1, 3, 5, 7, 12, 16-24, 26-36, 38, 40, 42, 47, 51-59, 61-65, 67, 69, 71, 76-88, 90, 92, 97, and 99 under 35 U.S.C. 103(a) as set forth in the last Office and presently maintained.
4. Claims 1, 3, 5, 7, 12, 16-24, 26-36, 38, 40, 42, 47, 51-59, 61-65, 67, 69, 71, 76-88, 90, 92, 97, and 99 are presently under consideration.
5. Applicant's arguments, filed 6/02/2009, have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either

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reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 3, 5, 7, 12, 16-24, 26-36, 38, 40, 42, 47, 51-59, 61-65, 67, 69, 71, 76-88, 90, 92, 97, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (U.S. Patent No. 6,224,848), in view of Wang (U.S. Patent No. 5,627,871).

Mills teaches *inter alia* a method for eliciting tissue necrosis, in treating *inter alia* cancer, by administering a compound (e.g., cisplatin) that binds to targeted tissue DNA, wherein said compound comprises an atom (e.g., platinum) that is excitable with radiation in a distinct narrow frequency band and energy level, causing an Auger electron cascade resulting in radiolysis of DNA. See Abstract and columns 108-110,

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claims 1, 5, and 9). Note that the compound, cis-diamminedichloroplatinum (II), taught by Mills in column 109, line 8, is the chemical name of cisplatin. Since cisplatin taught in the reference is the same as cisplatin recited by the instant invention, the properties of the elected compound (cisplatin) recited by the instant claims would also be encompassed by the cisplatin taught by Mills. For instance, the rate of physiological excretion of cisplatin and stability against dissociation of platinum from cisplatin during the time prior to complete excretion of cisplatin (e.g., instant Claims 16 and 17 respectively) would be identical in both the reference and the instant invention. Similarly, the K- and L-absorption edge of platinum and the amount of Auger electrons released from the platinum in cisplatin would be identical in the Mills reference and the instant claims.

The instant invention differs from the cited reference in that the cited reference does not teach the Applicant's preferred method of eliciting Auger electron cascade (i.e., line emission x-rays) from the selected element (i.e., platinum). However, the secondary reference, Wang, teaches the preferred line emission x-rays to be well known in the art. See column 10, lines 27-51. Wang teaches an end window transmission x-ray tube possessing a metal foil target on said end window, the thickness and composition of the metal foil target and the e-beam energy focused thereupon generate a micro-focused bright line beam x-rays of pre-selected energy. See Abstract.

Therefore, one skilled the art would have understood that the substitution of one monochromatic x-ray source (with distinct and specific frequency and energy level

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properties) for another source (with the same energy properties) would produce and achieve the same results (causing a Auger electron cascade from the platinum in the cisplatin) in the absence of evidence to the contrary. It would have been obvious to the artisan to use the x-ray source taught by Wang because of the increased convenience and logistics of using the smaller and more easily transported x-ray tube as opposed to the synchrotron taught by Mills.

The references do not teach the treatment of cells removed from and returned/transplanted back to a mammal. The references do not teach a kit comprising an x-ray tube having a target comprising a selected metal, and a compound (cisplatin) comprising a selected element (Pt).

One skilled in the art would have well versed in the practice of removing bone marrow and various other cells from the body for treating certain cancers (e.g., x-ray treatment) and returning/transplanting these cell back into the body. It would have been obvious to use the methods taught by Mills and modified by the teachings of Wang to seek an improved cancer therapy. It would also have been obvious to said artisan to “package” the essential components necessary to practice these methods. One would have been motivated to do so to provide a more convenient and efficient means for practicing a method of cancer therapeutics.

9. Applicant argues the Mills reference “teaches a therapy that relies upon Mossbauer absorption as an alternative to radiation with x-rays. As explained in the Wang Declaration, the emission and absorption of X-rays by gases, and the emission and absorption of gamma-rays in a solid under the Mossbauer effect initiated by a

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nuclear decay, are both very different from the Auger cascade and the Auger dose.”

Applicant alleges Mills irradiation source fails to “induce a large radiation dose *in situ* next to the target atom.” Applicant asserts the reference to Wang does not rectify the deficiencies of the Mills reference. Applicant argues “Wang does not show or suggest the use of line emission x-rays tuned to the K- or L- absorption edge of a selected element to create an Auger cascade that can be used selectively to destroy tumor cells **without destroying healthy tissue.**” (Emphasis by Applicant) Finally, Applicant argues Cash Jr. et al. (US Patent 6,366,801), which was not used by the Office in the rejection, teaches away from a method which generates a dose of at least  $10^6$ GY.”

Applicant’s arguments have been fully considered but have not been found persuasive. One skilled the art would have understood that the substitution of one monochromatic x-ray source (with distinct and specific frequency and energy level properties, such as in the teachings of Mills) for another source (with the same energy properties, such as in the teachings of Wang) would produce and achieve the same results (causing a Auger electron cascade from the platinum in the cisplatin) in the absence of evidence to the contrary. As presented *supra*, Mills teaches *inter alia* a method for eliciting tissue necrosis, in treating *inter alia* cancer, by administering a compound (e.g., cisplatin) that binds to targeted tissue DNA, wherein said compound comprises an atom (e.g., platinum) that is excitable with radiation in a distinct narrow frequency band and energy level, causing an Auger electron cascade resulting in radiolysis of DNA. It would have been obvious to the artisan to use the x-ray source taught by Wang because of the increased convenience and logistics of using the



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smaller and more easily transported x-ray tube as opposed to the synchrotron taught by Mills.

Cash teaches methods which differ from those of Mills and do not constitute a teaching away.

### ***Conclusion***

10. Claims 1, 3, 5, 7, 12, 13, 16-36, 38, 40, 42, 47, 48, 51-65, 67, 69, 71, 76-88, 90, 92 and 97-99 are rejected.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/  
Examiner, Art Unit 1614

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614